

**DATES:** Comments must be postmarked, or sent by telecopier (FAX) or electronic mail by January 31, 1995.

**ADDRESSES:** Comments must be submitted in writing to Janet M. Hart, Chief, Review Branch, Compliance Division, GIPSA, USDA, Room 1647 South Building, P.O. Box 96454, Washington, DC 20090-6454. SprintMail users may respond to [A:ATTMAIL,O:USDA,ID:A36]HART]. ATTMAIL and FTS2000MAIL users may respond to !A36]HART. Telecopier (FAX) users may send comments to the automatic telecopier machine at 202-720-1015, attention: Janet M. Hart. All comments received will be made available for public inspection at the above address located at 1400 Independence Avenue, S.W., during regular business hours.

**FOR FURTHER INFORMATION CONTACT:** Janet M. Hart, telephone 202-720-8525.

**SUPPLEMENTARY INFORMATION:**

This action has been reviewed and determined not to be a rule or regulation as defined in Executive Order 12866 and Departmental Regulation 1512-1; therefore, the Executive Order and Departmental Regulation do not apply to this action.

In the October 31, 1994, **Federal Register** (59 FR 54427, 54428), GIPSA asked persons interested in providing official services in the geographic areas assigned to Detroit, Jinks, Keokuk, and Michigan to submit an application for designation. There were four applicants. Detroit, Keokuk, and Michigan, each applied for designation to provide official inspection services in the entire area currently assigned to them. Jinks applied for designation to provide official Class X and Class Y weighing services in the entire area currently assigned to them. Springfield Grain Inspection, Inc., applied for the portion of Keokuk's area that includes all of Mason County and the part of Fulton County South of State Route 24.

GIPSA is publishing this notice to provide interested persons the opportunity to present comments concerning the applicants. Commenters are encouraged to submit reasons and pertinent data for support or objection to the designation of these applicants. All comments must be submitted to the Compliance Division at the above address. Comments and other available information will be considered in making a final decision. GIPSA will publish notice of the final decision in the **Federal Register**, and GIPSA will send the applicants written notification of the decision.

**AUTHORITY:** Pub. L. 94-582, 90 Stat. 2867, as amended (7 U.S.C. 71 *et seq.*)

Dated: December 22, 1994.

**Neil E. Porter,**

*Director, Compliance Division.*

[FR Doc. 94-32211 Filed 12-30-94; 8:45 am]

**BILLING CODE 3410-EN-F**

**Designation of the Grand Forks (ND), Lima (OH), and Virginia Areas**

**AGENCY:** Grain Inspection, Packers and Stockyards Administration (GIPSA).

**ACTION:** Notice.

**SUMMARY:** GIPSA announces the designation of Grand Forks Grain Inspection Department, Inc. (Grand Forks), Lima Grain Inspection Service, Inc. (Lima), and the Virginia Department of Agriculture and Consumer Services (Virginia) to provide official services under the United States Grain Standards Act, as amended (Act).

**EFFECTIVE DATES:** February 1, 1995.

**ADDRESSES:** Janet M. Hart, Chief, Review Branch, Compliance Division, GIPSA, USDA, Room 1647 South Building, P.O. Box 96454, Washington, DC 20090-6454.

**FOR FURTHER INFORMATION CONTACT:** Janet M. Hart, telephone 202-720-8525

**SUPPLEMENTARY INFORMATION:**

This action has been reviewed and determined not to be a rule or regulation as defined in Executive Order 12866 and Departmental Regulation 1512-1; therefore, the Executive Order and Departmental Regulation do not apply to this action.

In the August 1, 1994, **Federal Register** (59 FR 38954), GIPSA asked persons interested in providing official services in the geographic areas assigned to Grand Forks, Lima, and Virginia to submit an application for designation. Applications were due by August 30, 1994. Grand Forks, Lima, and Virginia, the only applicants, each applied for designation in the entire area they are currently assigned.

GIPSA requested comments on the applicants in the October 3, 1994 **Federal Register** (59 FR 50222). Comments were due by November 1, 1994. GIPSA received no comments by the deadline.

GIPSA evaluated all available information regarding the designation criteria in Section 7(f)(1)(A) of the Act; and according to Section 7(f)(1)(B), determined that Grand Forks, Lima, and Virginia are able to provide official services in the geographic areas for which they applied. Effective February 1, 1995, and ending January 31, 1998, Grand Forks and Lima are designated to provide official inspection services in the geographic areas specified in the

August 1, 1994, **Federal Register**.

Effective February 1, 1995, and ending January 31, 1998, Virginia is designated to provide official inspection and Class X and Class Y weighing services in the geographic area specified in the August 1, 1994, **Federal Register**.

Interested persons may obtain official services by contacting Grand Forks at 701-772-0151, Lima at 419-223-7866, and Virginia at 703-434-1387.

**AUTHORITY:** Pub. L. 94-582, 90 Stat. 2867, as amended (7 U.S.C. 71 *et seq.*)

Dated: December 21, 1994

**Neil E. Porter**

*Director, Compliance Division*

[FR Doc. 94-32212 Filed 12-30-94; 8:45 am]

**BILLING CODE 3410-EN-F**

**DEPARTMENT OF COMMERCE**

**Patent and Trademark Office**

[Docket No. 941259-4359]

**Request for Comments on Proposed Utility Examination Guidelines**

**AGENCY:** Patent and Trademark Office, Commerce.

**ACTION:** Notice and request for public comments.

**SUMMARY:** The Patent and Trademark Office (PTO) requests comments from any interested member of the public on proposed internal guidelines that will be used by patent examiners in their review of patent applications for compliance with 35 U.S.C. 101. Because these guidelines govern internal practices, they are exempt from notice and comment rulemaking under 5 U.S.C. 553(b)(A).

**DATES:** Written comments on the proposed guidelines will be accepted by the PTO until February 24, 1995.

**ADDRESSES:** Written comments should be addressed to the Commissioner of Patents and Trademarks, marked to the attention of Jeff Kushan. Comments submitted by mail should be sent to Commissioner of Patents and Trademarks, Box 4, Patent and Trademark Office, Washington, DC 20231. Comments may also be submitted by telefax at (703) 305-8885 and by electronic mail through the Internet to "comments-biotech@uspto.gov." Written comments should include the following information:

- Name and affiliation of the individual responding;
- An indication of whether comments offered represent views of the respondent's organization or are the respondent's personal views; and

—If applicable, information on the respondent's organization, including the type of organization (e.g., business, trade group, university, non-profit organization) and general areas of interest.

Parties presenting written comments are requested, where possible, to provide their comments in machine readable format. Such submissions may be provided by electronic mail messages sent over the Internet, or on a 3.5" floppy disk formatted for use in either a Macintosh or MS-DOS based computer. Machine-readable submissions should be provided as unformatted text (e.g., ASCII or plain text).

Written comments will be available for public inspection on or about March 1, 1995, in Room 902 of Crystal Park Two, 2121 Crystal Drive, Arlington, Virginia. In addition, comments provided in machine readable format will be available on or around March 1, 1995, through anonymous file transfer protocol (ftp) via the Internet (address: comments.uspto.gov) and through the World Wide Web (address: www.uspto.gov).

**FOR FURTHER INFORMATION CONTACT:** Jeff Kushan by telephone at (703) 305-9300, by fax at (703) 305-8885, by electronic mail at kushan@uspto.gov, or by mail marked to his attention addressed to the Commissioner of Patents and Trademarks, Box 4, Washington, DC 20231.

#### **SUPPLEMENTARY INFORMATION:**

### **I. Guidelines for Examination of Applications for Compliance With the Utility Requirement**

#### *A. Introduction*

The following guidelines establish the policies and procedures to be followed by Examiners when examining applications for compliance with the utility requirement of 35 U.S.C. 101. The guidelines also address issues that may arise during examination of applications claiming protection for inventions in the field of biotechnology and human therapy. The guidelines are accompanied by an overview of applicable legal precedent governing the utility requirement.

#### *B. Guidelines for Examination of Applications for Compliance With 35 U.S.C. 101*

Examiners must adhere to the following procedures when examining applications for compliance with 35 U.S.C. 101.

1. Determine what the applicant has claimed as his or her invention. This is done to:

(a) Ensure that the applicant has claimed statutory subject matter (e.g., a process, a machine, a composition or a manufacture); and

(b) Ascertain what the invention is for, purposes of determining whether it is "useful."

2. Review the specification and claims to determine if the applicant has disclosed or asserted any credible utility for the claimed invention.

(a) If the applicant has asserted that the claimed invention is useful for any particular purpose and that assertion would be considered credible by a person of ordinary skill in the art, the Examiner should not impose a rejection based on section 101. Credibility is to be assessed from the perspective of one of ordinary skill in the art in view of any evidence of record (e.g., data, statements, opinions, references, etc.) that is relevant to the applicant's assertions.

(b) If the applicant has not asserted that the claimed invention is useful for a particular purpose but such a use would be readily apparent to a person of ordinary skill in the art, the Examiner should not impose a rejection under section 101.

3. If the applicant has not asserted any credible utility for the claimed invention or a utility would not be readily apparent to one of ordinary skill in the art, reject the claims under section 101. To be considered appropriate by the Office, a rejection under section 101 must include the following elements:

(a) A prima facie showing that the claimed invention has no utility. A prima facie showing of no utility must establish that it is more likely than not that a person of ordinary skill in the art would not consider credible any utility for the claimed invention that has been asserted by the applicant. Where no utility has been asserted in the disclosure, the prima facie showing must support a finding that a person of ordinary skill would not be able to ascertain any use for the claimed invention. A prima facie showing must contain:

(i) A well-reasoned statement by the Examiner that clearly sets forth the reasoning used in reaching his or her conclusions;

(ii) Support for factual findings relied upon by the Examiner in reaching his or her conclusions; and

(iii) Support for conclusions of the Examiner that evidence provided by the applicant to support an asserted utility would not be considered persuasive to a person of ordinary skill in the art.

(b) Evidence that supports any factual assertions relied upon by the Examiner in establishing the prima facie showing.

Whenever possible, the Examiner must provide documentary evidence that supports the factual basis of a prima facie showing of no utility (e.g., scientific or technical journals, excerpts from treatises or books, or U.S. or foreign patents). If documentary evidence is not available, the Examiner should note this fact and specifically explain the scientific basis for his or her conclusions.

4. A rejection under section 101 should not be maintained if an asserted utility for the claimed invention would be considered credible by a person of ordinary skill in the art in view of all evidence of record.

Once a prima facie showing of no utility has been properly established, the applicant bears the burden of rebutting it. The applicant can do this by amending the claims, by providing reasoning or arguments, or by providing evidence in the form of a declaration under 37 CFR 1.132 or a printed publication, that rebuts the prima facie showing. Once a response has been received by the Examiner, he or she should review the original disclosure, any evidence relied upon in establishing the prima facie showing, any claim amendments and any new reasoning or evidence provided by the applicant in support of an asserted utility. It is essential that the Examiner recognize, fully consider and respond to each substantive element of any response to a rejection under section 101.

Examiners are reminded that they must treat as true credible statements made by an applicant or a declarant in the specification or in a declaration provided under 37 CFR 1.132, unless they can show that one of ordinary skill in the art would have a rational basis to doubt the truth of such statements. Thus, not accepting the opinion of a qualified expert that is based on an appropriate factual record would clearly be improper.

### **II. Additional Information**

The PTO has prepared an analysis of the law governing 35 U.S.C. 101 to support the guidelines outlined above. Interested members of the public are invited to comment on the legal analysis as well as the guidelines. Copies of the legal analysis can be obtained from Jeff Kushan, who can be reached using the information indicated above.

Dated: December 23, 1994.

**Bruce A. Lehman,**

*Assistant Secretary of Commerce and  
Commissioner of Patents and Trademarks.*

[FR Doc. 94-32314 Filed 12-30-94; 8:45 am]

**BILLING CODE 3510-16-M**